

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

**INFORMATION DISCLOSURE  
STATEMENT**

Docket Number:  
**2664/571022**

Application Number  
**Not Yet Assigned**

Filing Date  
**Herewith**

Examiner  
**Solola Taofiq A**

Art Unit  
**1626**

Invention Title  
**NOVEL PROCESS FOR PREPARING RAC-  
BICALUTAMIDE AND ITS INTERMEDIATES**

Inventors  
**DOLITZKY Ben-Zion, et al.**

Address to:  
Mail Stop Patent Application  
Commissioner for Patents  
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Alexandria, VA 22313-1450

1. In accordance with the duty of disclosure under 37 C.F.R. § 1.56 and in conformance with the procedures of 35 U.S.C. §§ 1.97 and 1.98 and M.P.E.P. § 609, attorneys for Applicants hereby bring the following references to the attention of the Examiner. These references are listed on the attached modified PTO Form No. 1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b).
2. Copies of each patent, publication or other information listed on the modified PTO Form 1449 are not enclosed since they were previously cited by or submitted to the Patent Office in a prior application, Serial No. 10/170,721, which is relied upon for an earlier filing date under 35 U.S.C. § 120.

Dated: 3/1/04

By: \_\_\_\_\_

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	<b>DOCKET NO.</b> 2664/571022	<b>SERIAL NO</b> Unknown
	<b>APPLICANT</b> Dolitzky et al.	
	<b>FILING DATE</b> Herewith	<b>GROUP</b> 1626

**U. S. PATENT DOCUMENTS**

EXAMINER INITIAL	PATENT NUMBER	PATENT DATE	NAME	CLASS	SUBCLASS	FILING DATE
	4,636,505	January 13, 1987	Tucker			
	6,358,985	March 19, 2002	Anthony et al.			
	6,306,874	October 23, 2001	Fraley et al.			
	6,291,504	September 18, 2001	Nugiel et al.			
	6,184,249	February 6, 2001	Sovak et al.			
	6,160,011	December 12, 2000	Miller et al.			
	4,554,381*	November 19, 1985	Desbois			
	5,723,485*	March 3, 1998	Gungor et al.			
	3,254,094*	May 31, 1966	Ross			

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 93/19770	Oct. 14, 1993	PCT			x	
	WO 01/00608	Jan. 4, 2001	PCT			x	

**OTHER DOCUMENTS**

EXAMINER INITIAL		AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
		MacPeck, Donald L. et al., "Synthesis of Glycidic Esters by Epoxidation of $\alpha,\beta$ -Unsaturated Esters With Peracetic Acid," J. Am. Chem., 1959, Vol. 81, pp. 680-683.
		Emmons, William D. et al., "Peroxytrifluoroacetic Acid. IV. The Epoxidation of Olefins," J. Am. Chem., 1955, Vol. 77, pp. 89-92.
		Ho, Winston et al., "Alkylglycidic Acids: Potential New Hypoglycemic Agents," J. Med. Chem., 1986, Vol. 29, pp. 2184-2190.
		Lieberman, Herbert A. et al., <u>Pharmaceutical Dosage Forms: Tablets</u> , Volume 2, 2 <sup>nd</sup> Ed., Marcel Dekker, Inc. New York (1990), pp. 107-200.
		Database CAPLUS on STN, Chemical Abstracts, CA: 129:244921, Freskos et al., "Preparation of aromatic sulfonyl alpha-hydroxy hydroxamic acid compounds as matrix metalloprotease inhibitors" *
		Database CAPLUS on STN, Chemical Abstracts, CA:128:75188, Takahashi et al., "Preparation and formulation of aryl sulfides, sulfoxides, and sulfones as matrix metalloproteinase inhibitors" *
		Database CAPLUS on STN, Chemical Abstracts, CA: 136:12767, Slusarek et al., "Color photographic thermally processable film comprising blocked developer compound" *

EXAMINER INITIAL		AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
		Database CAPLUS on STN, Chemical Abstracts, CA: 86:171116, Buettner et al., "Trifluoromethyl-substituted aminobenzonitriles" *
		Database CAPLUS on STN, Chemical Abstracts, CA: 108:150026, Tucker et al., "Resolution of the non-steroidal antiandrogen 4'-cyano-3-(4-fluorophenylsulfonyl)-2-hydroxy-2-methyl-3'-(trifluoromethyl) propionanilide and the determination of the absolute configuration of the active enantiomer" *
		Database CAPLUS on STN, Chemical Abstracts, CA: 2002:414656, James et al., "A two-step synthesis of the anti-cancer drug (r,S)-bicalutamide" *
		Database CAPLUS on STN, Chemical Abstracts, CA:120:191513, Horschler von Locquenghien et al., "Preparation of oxiranecarboxylates and analogs" *
		Database CAPLUS on STN, Chemical Abstracts, CA:89:90113, Rastetter, et al. "3,5-Dinitroperoxybenzoic acid. A crystalline, storable substitute for peroxytrifluoroacetic acid" *
		Database CAPLUS on STN, Chemical Abstracts, CA:134:326279, Ekwuribe, et al. "Asymmetric synthesis and antiandrogenic use of enantiomers of Casodex (bicalutamide) and derivatives from enantiomers of citramalic acid or proline"

\* cited in an International Search Report, a copy is attached herewith

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	